Discussion of Staff's Disposition of Comments Received in Response to the Staff's Proposal

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ATTACHMENT 2

I. Background

As stated in the main body of this document, the staff held a facilitated and transcribed public workshop on August 25, 2003, and issued a *Federal Register* notice (FRN) on July 24, 2003 (68 FR 43767), soliciting comments on its proposal on programmatic inspections, tests, analyses, and acceptance criteria (ITAAC). The staff received three comment letters from industry in response to the FRN. This attachment provides a discussion of the main points made at the August 25, 2003, workshop and also addresses the key issues identified in the three letters from industry.

The August 25, 2003, corrected transcripts, the August 25, 2003, meeting summary and the industry's three comment letters are available in the Agencywide Documents Access and Management Systems (ADAMS) in the Nuclear Regulatory Commission (NRC) Public Document Room located at One White Flint North, 11555 Rockville Pike, Public File Area O1F21, Rockville, Maryland. The information is also available electronically from the Publicly Available Records (PARS) component of ADAMS. The ADAMS accession numbers for the documents are as follows:

- August 25, 2003, meeting summary - ADAMS Accession No. ML032530004
- August 25, 2003, corrected transcripts - ADAMS Accession No. ML032530003
- September 15, 2003, letter from Ron Simard, Nuclear Energy Institute - ADAMS Accession No. ML032690843
- September 15, 2003, letter from George A. Zinke, Entergy Nuclear Inc. - ADAMS Accession No. ML032661176
- September 15, 2003, letter from L. B. Long, Southern Nuclear Operating Company - ADAMS Accession No. ML032661172

ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* (the Public Electronic Reading Room). For more information, contact the NRC Public Document Room (PDR) reference staff at 1-800-397-4209 or 202-634-3273 or by e-mail to pdr@nrc.gov.

II. August 25, 2003, Workshop Comments

Several key issues were discussed during the workshop on August 25, 2003. The workshop was in the form of a roundtable discussion facilitated by Chip Cameron of the NRC's Office of the General Counsel. Although the focus of the meeting was on the roundtable discussion, there were opportunities for members of the audience to offer comments and ask questions. The members of the roundtable are listed below.

Name	Organization	Name	Organization
James Lyons	NRC, Program Director - New, Research and Test Reactors (RNRP)	David Ritter	Public Citizen's Critical Mass Energy and Environmental Program
Jerry Wilson	NRC, RNRP	Paul Gunter	Nuclear Information and Resource Service
Joe Sebrosky	NRC, RNRP	Eddie Grant	Exelon

Name	Organization	Name	Organization
Russ Bell	Nuclear Energy Institute (NEI)	Al Passwater	Polestar
Ben George	Southern Nuclear	Ron Simard	NEI

The roundtable discussion addressed issues from individuals representing the citizens groups and those from industry.

II.a Citizens Group Comments

A key issue for both of the representatives of citizens groups was a concern for the quality of public participation during the Part 52 process. Another concern of one of the citizens groups was the change process associated with ITAAC.

II.a.1 Quality of Public Participation

Both citizens group representatives stated that they were interested in meaningful opportunities for the public to participate in the 10 CFR Part 52 licensing process. The staff noted that the ITAAC are determined in the proceeding on the application for a combined license (COL), which is a mandatory hearing with an associated opportunity for public participation. The staff also noted that this mandatory hearing would be completed before construction of the reactor could begin. The staff stated that after this mandatory hearing, if the COL is granted, the reactor can be constructed and the NRC can verify if the ITAAC have been successfully completed. The staff also stated that after construction is complete or nearly complete, there is an opportunity for a hearing in accordance with 10 CFR 52.103, and the staff discussed the importance of ITAAC in the process. The staff noted that a request for a hearing in accordance with § 52.103 is limited to whether the acceptance criteria contained in the ITAAC have been met.

The industry representatives noted that absent ITAAC, interested parties or people have other opportunities to express their concerns. One of these opportunities that was noted was that the public could use the 10 CFR 2.206 petition process to raise concerns. A response from a citizens group representative was that public participation is “considerably degraded” under 10 CFR 2.206.

Supplemental Staff Response

The concern regarding public participation during the 10 CFR Part 52 licensing process is consistent with the concerns that were raised during the rulemaking for Part 52. SECY-02-0067, “Inspections, Tests, Analyses, and Acceptance Criteria for Operational Programs (Programmatic ITAAC),” dated April 15, 2002, noted that the 1989 statements of consideration for the final rule stated that “[t]he deepest differences among the commenters concern the consequences of standardization and other devices for early resolution of licensing issues for the licensing process. . . . Many of the commenters attribute to the Commission an intent to do away with public participation in the licensing process.”

As noted in SECY-02-0067, the Commission's response, as documented in the statements of consideration for the 1989 rule, was the following:

> The Commission has given more consideration to this issue than to any other procedural question raised by the proposed rule. As a result, the proposed rule's provisions on hearings just before operation have been revised in the final rule . . . . However, the final rule still provides for an opportunity for a hearing on limited issues before operation under a combined license. But the mere fact of this opportunity does not mean that the rule is hiding the old two-step process under a different name. By far the greater part of the issues which in the past have been considered in operating license hearings would, under the new rule, be considered at the combined license stage or in a certification proceeding, including the bulk of emergency planning issues. Similarly, the mere fact that any hearing prior to operation would be limited does not mean that the Commission is attempting to remove the public from the licensing process. The rule does not prevent the public from participating in the resolution of any operating license issue. It simply moves the bulk of the issues up front in the licensing process to the design certification, early site permit, and combined license parts of the process.

The staff believes that the proposal contained in the main body of this document is consistent with the intent of 10 CFR Part 52 and the Commission's staff requirements memorandum (SRM) dated September 11, 2002. By reviewing and inspecting implementing procedures for certain programs before the issuance of the combined license, the staff is moving these issues up front in the licensing process. Because such information would be reviewed prior to a decision on whether to grant a COL, it could be the subject of the mandatory hearing on the COL application. The staff believes that by reviewing and inspecting such procedures before making a determination on whether to grant a COL, the staff would not need ITAAC to verify implementation of the fire protection operational program.

Industry expressed a concern that if the procedures were developed and approved in the COL proceeding, they would become part of the "licensing basis" and expand the information that is contained in the final safety analysis report (FSAR). The staff mentioned during the meeting that Part 52 does have a provision that allows the application to include information that is not otherwise included in the FSAR. The staff also discussed the idea of reviewing the procedures on site and making the results of the inspections publicly available in an inspection report. Similar processes have been used during design certification reviews. That is, the staff inspected information that was used to support an application without having the actual information on the docket. However, the results of such inspections were placed on the docket either in the safety evaluation report or an inspection report.

A citizens group representative stated that by not having the procedures on the docket and publicly available, they would not have the chance to review them and determine if they had any issues associated with them. The staff responded by stating that for operating reactors today most operating procedures are not available publicly. However, the results of staff inspections of the operating procedures are made publicly available through inspection reports.

The staff intends to explore the issue of the status of the operating procedures further if the Commission approves the position outlined in the main body of this document. The staff will

discuss with stakeholders whether or not the procedures need to be submitted with the application to obviate the need for ITAAC or if it is sufficient to have the procedures available for inspection during the staff's review of the COL application.

II.a.2 Change Process Associated with ITAAC

A member of a public citizens group questioned how ITAAC could be changed after they had been agreed to by the staff. The person wanted to know how malleable ITAAC were and if public participation was possible if the ITAAC were changed after a COL was issued.

The staff responded during the meeting that once ITAAC are approved and incorporated into a COL, they are not intended to be easily changed. The staff stated that for a COL applicant or licensee there were several possibilities and the public participation afforded depended on where in the process the ITAAC change was made.

Supplemental Staff Response

The NRC has issued a brochure, NUREG/BR-0298, "Nuclear Power Plant Licensing Process," which discusses the 10 CFR Part 52 licensing process and opportunities for public involvement.

ITAAC Developed During 10 CFR Part 52 Standard Design Certifications

If a public interest group chooses, it may become involved in the development of ITAAC. This can be done either during the public meetings held with the staff and the applicant during the staff's review of the application, which includes the development of the safety evaluation report for the design, or during the administrative review of the design certification application. The public meetings that are held between the staff and the applicant are conducted in accordance with the Commission's policy statement on "Enhancing Public Participation in NRC Meetings," dated May 28, 2002 (67 FR 36920). This policy statement allows for members of the public, including public interest groups, if they so choose, to obtain factual information about the design, and also allows for the public to communicate with the staff after the business portion of the meeting, but before the meeting is adjourned. The administrative review is performed after the staff has made a determination on the acceptability of the design and is done as part of the process to codify the design as a rule. For example, Appendix A of 10 CFR Part 52 is the design certification rule for the U.S. Advanced Boiling Water Reactor.

The administrative review of a design certification application is governed by 10 CFR 52.51. Section 52.51 was affected by the Commission's recent amendment to its Rules of Practice in 10 CFR Part 2 to make the NRC's hearing process more effective and efficient. The final rule was effective February 13, 2004, and is discussed in a FRN dated January 14, 2004 (69 FR 2182). The new section 52.51 states in part that "the notice of proposed rulemaking in the FRN must provide an opportunity for the submission of comments on the proposed design certification rule."

Changes to ITAAC Contained in a Certified Design

A COL applicant may choose to reference a certified design in its application. If it chooses such an approach, any ITAAC that were developed, reviewed, approved and codified during the

design certification process would not normally be reconsidered. However, there is a change process for ITAAC that fall into this category.

The certified designs are codified in regulations and are contained in appendices to 10 CFR Part 52 as discussed above. 10 CFR Part 52, Appendix A, Section VIII, "Processes for Changes and Departures," discusses the change process associated with Tier 1 information. Tier 1 information includes the ITAAC for the design. The changes that are possible are generic changes to Tier 1 information and plant-specific exemptions from Tier 1 information, as well as plant specific orders changing such information. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1). The new section that is effective February 13, 2004, states:

> [T]he Commission may not modify, change, rescind, or impose new requirements on the certification, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that a modification is necessary to either bring the certification or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate public health and safety or the common defense and security. The rulemaking procedures must provide for notice and opportunity for public comment.

Therefore the public has the opportunity to comment during the rulemaking process.

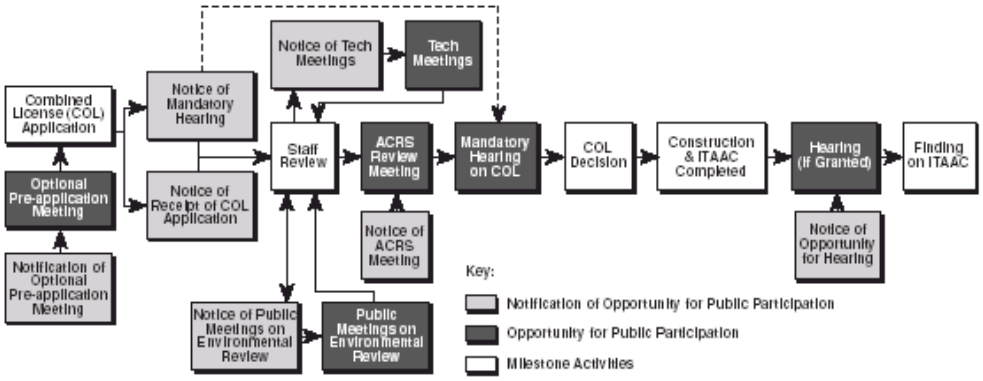
The Commission may also issue a plant-specific order for a certified design in accordance with 10 CFR 52.63(a)(3). There would be an opportunity to request a hearing in connection with any such plant-specific order, just as there is for any enforcement proceeding.

Section VIII.A.4 of the certified design rules discusses changes through exemptions that are made to the ITAAC that are part of the certified design. An applicant or licensee who references a certified design may seek an exemption from one or more elements of the design certification. Such exemptions may be sought before or after a COL is issued. The change process for exemptions is governed by 10 CFR 52.63(b)(1) and 10 CFR 52.97(b). These sections state that the granting of an exemption must be subject to litigation in the same manner as other issues in the operating license or COL hearing.

ITAAC Submitted as Part of a COL application

Figure 4 of NUREG/BR-0298 provides a diagram of public involvement during the review of a combined license and is included below for reference. Any ITAAC that are submitted as part of a COL application, such as those related to emergency planning, would be subject to the mandatory hearing on the COL application in accordance with 10 CFR 52.85. During this process, interested members could seek to intervene in the proceeding and challenge the wording of ITAAC or the lack of ITAAC for those issues that are reviewed during that proceeding. The amount of material that is subject to the hearing depends on what issues have previously been decided and afforded finality. For example, if a COL application references a certified design, ITAAC associated with that design would not normally be the subject of the COL hearing unless an exemption is requested as discussed above.

Figure 4 - Opportunities for Public Involvement During the Review of Combined Licenses



Regardless of whether a COL references a certified design, the issue of ITAAC associated with operational programs is subject to litigation in accordance with 10 CFR 52.85. This is because operational programs are reviewed at the COL stage. If an interested party believes that ITAAC are needed for a particular operational program and none are provided in the COL application, the chance to raise the issue in a hearing by the interested party is afforded by the Notice of Hearing on the COL application. Once this hearing on the COL is completed, the finding on the ITAAC is made and it is the intent of the 10 CFR Part 52 process that the ITAAC remain unchanged except in limited circumstances.

II.b Industry Comments

During the August 25, 2003, workshop Nuclear Energy Institute (NEI) and industry officials raised several issues, most of which were reiterated in the response letters to the FRN. There were areas of agreement that were identified during the workshop that were not included in the response letters. The areas of agreement are discussed below. The major disagreements with the staff's proposal that NEI and industry discussed during the August 25, 2003, workshop were also captured in the written responses to the FRN. Therefore, the areas of disagreement are discussed in Section III of this attachment.

II.b.1 Categorization of the Programs

NEI did not object to a portion of the proposal contained in the main body of this document. Namely, during the August 25, 2003, workshop NEI did not object to Category A, Category B, Category C, or Category E for the programs. During the August 25, 2003, workshop NEI noted the following about these categories:

- NEI recognized that emergency planning will most likely require ITAAC in accordance with the Commission's direction in the staff requirements memorandum (SRM). The staff's proposal placed emergency planning in Category A - that is, programmatic ITAAC are required. Although NEI did not think that it was a good idea to have emergency planning ITAAC, NEI conceded that emergency planning ITAAC would likely need to be developed.

- NEI also indicated that there was no disagreement with Category B of the staff's proposal, namely that programmatic ITAAC are not necessary for certain programs because hardware-related ITAAC address the results to which the program is directed.

- Regarding Category C programs, NEI stated that it believed this category was consistent with the Commission's direction in the SRM that programmatic ITAAC are not necessary because the program and its implementation can be fully described in the application and found to be acceptable at the COL stage.

- NEI also indicated that it agreed that ITAAC are not necessary for Category E programs because ITAAC will be dispositioned prior to fuel load and such a program is not required to be implemented until after fuel load. NEI did question why this category was not more broadly applied to other programs (see Section III.d of this attachment for more discussion of this issue).

II.b.2 Some Programmatic Information To be Supplied at the COL Stage

There was general agreement on some of the information that should be supplied at the COL stage for the fire protection program. Specifically, there was general agreement with the staff's proposal that the following information should be provided for the fire protection program at the COL stage in order to issue a COL without ITAAC for that program:

1. The information in the referenced designed control document (DCD) or the applicable analogous information that addresses the COL action items contained in the DCD.

2. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 of the SNUPPS Standard Plant FSAR (and the applicable appendices) for the Callaway Plant.

3. Fire protection program information at a level of detail similar to that contained in Section 9.5.1 (and the applicable appendices) of the Site Addendum portion of the FSAR for the Callaway Plant.

NEI's handouts at the meeting, which are also attached to its comment letter, provided FSAR Section 9.5.1, "Fire Protection System," for a combined license application for the first AP-1000

plant or "AP-1000-1." As described during the meeting, NEI's response appears to be consistent with this portion of the staff's proposal. In response to a question from the staff at the August 25, 2003, workshop, an industry panelist who developed the AP-1000-1 FSAR Section 9.5.1 stated that it is roughly equivalent to the level of information that is in the current Callaway FSAR. The example also specifically addresses the AP600 COL action items contained in the design control document. The staff has not reviewed the AP-1000-1 COL FSAR proposed by NEI in detail, but at a high level the staff noted in the meeting that the FSAR appears to be consistent with this portion of the staff's proposal. The staff noted that there were areas such as for administrative controls where the Callaway FSAR had more detail than NEI's proposal. However, the staff believes that, given time, it could come to agreement with NEI on the level of FSAR information needed to address the first three issues identified in the staff's proposal regarding the level of information expected to be supplied in the COL application.

II.b.3 Fire Protection License Condition

The staff proposed that the COL applicant have a license condition similar to Callaway License Condition 2.C(5)(d) for the fire protection program:

> The licensee may make changes to the approved fire protection program without prior approval of the Commission only if those changes would not adversely affect the ability to achieve and maintain safe shutdown in the event of a fire.

SECY-00-0092, "Combined License Review Process," dated April 20, 2000, contains a proposed generic COL. The Commission approved the form and content of this generic COL in an SRM dated September 5, 2000. However, the proposed generic COL did not contain a fire protection program license condition similar to that contained in Callaway's license or discussed in GL 86-10, "Implementation of Fire Protection Requirements." The staff's proposal in Attachment 1 of this paper contains a COL license condition for the fire protection program. The industry did not object to this portion of the staff's proposal during the workshop or in its written comments. The staff believes after discussions with interested stakeholders on other COL issues that the generic combined license contained in SECY-00-0092 may need to be revised. The staff will collect these issues, revise the generic combined license, and inform the Commission in a separate paper.

III. Written Comments

All three industry commenters agreed that the principal issue is what information is necessary to fully describe a program and its implementation. Other issues that the industry raised in the meeting and in their letters include:

- use of training program as an example
- litigation risk associated with the post-construction hearing
- the justification for the staff not proposing ITAAC for the inservice inspection and inservice testing program should be more broadly applied

III.a Concerns Related to the Definition of "Fully Described"

NEI stated in its letter that "two key questions need to be addressed to determine the nature of operational information that must be provided in [a] COL application or otherwise available for NRC review":

1. What will provide reasonable assurance that operational programs, such as fire protection, will meet NRC requirements and provide adequate protection of public health and safety.

2. What type and level of information on program implementation is needed to support NRC reasonable assurance finding(s) at the COL stage.

The issue involves the interpretation of the term "fully described" in the following sentence contained in the Commission's SRM dated September 11, 2002:

> Although the NRC inspection process does not replace a particular ITAAC, an ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage.

NEI's and industry's comments relate to Category C and D programs that are identified in the staff's proposal contained in the main body of this paper. The staff listed eight programs that could fall into either category based on whether the program and its implementation can be "fully described" in the application. The staff's proposal includes guidelines for the fire protection program for the level of programmatic information that would be needed in order to issue a COL without ITAAC for that program. The staff's proposal used Callaway as an example and included fire protection implementing procedures unique to the fire protection program.

The industry objects to the fire protection program example and the fire protection procedures that the staff references in the proposal. Specifically, the industry does not believe it is necessary to provide information similar to the seven Callaway procedures (which along with the Callaway FSAR material constitute the fire protection program documents for Callaway) at the time of a COL application. Nor does the industry believe that it is necessary to provide fire protection implementing procedures unique to the fire protection program at the time of the COL application (the staff's proposal references seven Callaway procedures as examples).

In written as well as oral comments made during the August 25, 2003, workshop, industry representatives stated that they do not believe the Commission intended by its September 11, 2002, SRM that, for the NRC to grant a COL without ITAAC on programs, a COL applicant should provide more operational program information than that which is "necessary and sufficient" for the NRC staff to make its reasonable assurance finding(s) on the acceptability of the programs. NEI states in its letter that it "disagree[s] strongly" with the staff's

conclusion that it is necessary that some procedure-level information be provided or available to the NRC to support review of a COL application. NEI also stated the following in its letter:

> It is not necessary to provide procedure-level information to support the findings required for COL, nor is it practical for COL applicants to develop such information prior to COL issuance.

In addition, Southern Company stated in its letter that program descriptions similar to those contained in current final safety analysis reports will be sufficient to support reasonable assurance findings by the NRC staff.

Difficulty in Supplying Procedures at the COL Stage

In addition to objecting to providing the procedure-level information at the time of a COL application, NEI also stated that providing such procedure-level information at the time of the COL application would be difficult. During the workshop, the staff explained its position that procedure-level information on operational programs could be provided at the COL stage based on the belief that new units would be proposed for locations next to operating plants. Therefore, the staff believed that COL applicants could have available and could provide program procedures based on the nearby plant. NEI stated during the meeting, and reiterated in its written response, that with the exception of the fitness-for-duty program, most programs have design dependencies. NEI stated that these man-machine interface issues are typically addressed at the procedure level, such that procedures for nearby plant units could not be provided to support NRC review of the COL application for a future plant. In essence, NEI asserts that program implementation depends on the design details of plant structures, systems, and components, and plant personnel's treatment of these design details.

In addition, during the August 25, 2003, meeting, NEI indicated that COL applicants will not have plant staff in place to write the procedures for some programs, such as fire protection, until after the COL is issued. NEI also stated that procedure development is an iterative process that parallels plant construction, with newly hired plant staff, some of whom will write the procedures, on which others will be trained and drilled, revealing problems with the procedures. NEI argues that the procedures will be repeatedly revised during program implementation.

Staff Response

The staff believes that the key issues are:

- What information is necessary to fully describe a program and its implementation in the staff's definition of a Category C program such that an ITAAC is not necessary?

- Is procedure-level information for a program necessary at the COL stage in order to issue a COL without ITAAC for verification of that program?

The issue is not what information is necessary to provide a reasonable assurance finding with respect to program adequacy at the COL stage. Rather, the issue is what additional information is needed, if any, to issue a COL without ITAAC to verify the adequacy of implementation of an operational program. The staff is in general agreement with NEI about

the type of information that would need to be provided to meet NRC requirements for programs with ITAAC (i.e., the information described in Section II.b.2 above). The staff believes that additional information beyond what would normally be provided in an FSAR is needed in order to meet the direction in the Commission's SRM to fully describe the program and its implementation and to issue a COL without ITAAC for such a program. Under the Part 50 licensing process, the staff would review the FSAR to determine program acceptability and would subsequently inspect program development and implementation. Staff findings on these matters were necessary prerequisites to making the findings under 10 CFR 50.57 for issuance of an operating license under 10 CFR 50.57.

The staff believes that to issue a COL **without ITAAC** for verification of adequate implementation of an operational program, a review of the type of information provided in the implementing procedures for that program is necessary. Part of the set of fire protection procedures are those similar to that contained in the following Callaway Plant fire protection program procedures:

- APA-ZZ-00700, "Fire Protection Program"
- APA-ZZ-00701, "Control of Impairments of Fire Protections Systems and Components"
- APA-ZZ-00703, "Fire Protection Operability Criteria and Surveillance Requirements"
- APA-ZZ-0741, "Control of Combustible Materials"
- APA-ZZ-00742, "Control of Ignition Sources"
- APA-ZZ-00743, "Fire Team Organization and Duties"
- EDP-ZZ-04044, "Fire Protection Reviews"

The basis for the staff asking for the information that is provided in these procedures is contained in APA-ZZ-00700. Appendix 2 to this procedure lists Callaway FSAR information and the above procedures as "fire protection program documents."

In addition to this information, the staff would expect to review other fire protection implementing information unique to the fire protection program. Examples include information similar to the information found in the following Callaway Plant procedures:

- EIP-ZZ-00226, "Fire Response Procedure for the Callaway Plant"
- FPP-ZZ-0XXXX, "Series of Procedures, Pre-Fire Strategy Procedures"
- FPP-ZZ-00009, "Fire Protection Training Program"
- HTP-ZZ-05006, "Fire Involving Radioactive Material or Entry into the RCA"
- SDP-KC-00002, "Fire Door Position Verification"
- MSM-ZZ-FG002, "Fire Damper Inspection and Drop Test"
- QSP-ZZ-65045, "Fire Barrier Penetration Seal Visual Inspection"

In order to perform a review of an application and consider issuing a COL without ITAAC for verification of adequate implementation of an operational program, a description of how the program will be implemented, similar to the information found in the above procedures should be available. If the information cannot be made available because of resource and design-related issues during the review of the COL application, then providing ITAAC for that program would be acceptable. Consistent with the staff's proposal, this would place such programs in Category D - ITAAC for a program or elements of the program are necessary because the program and its implementation cannot be fully described in the application.

Need for Implementing Procedures

NEI's letter notes the following regarding implementing procedures:

> Fire Protection Program procedures must be developed and made available for review when it is time for the NRC staff to inspect Fire Protection Program implementation prior to operation. As indicated by Fire Protection Inspection Procedure 64704, NRC review of detailed procedures is important to enable the staff to understand how program requirements are being met and to verify the adequacy of implementation. However, these implementation details are not necessary prior to COL issuance to support licensing reviews based on the standard review plan (SRP) and the associated reasonable assurance findings on program acceptability

The staff agrees with some of NEI's statements and disagrees with others. Inspection Manual Chapter (IMC) 2513, "Light Water Reactor Inspection Program - Preoperational Testing and Operational Preparedness Phase," dictated the timing of various inspections, including those related to fire protection, during the operating license review under 10 CFR Part 50. (IMC-2513 is no longer an actively maintained IMC; however, the staff believes the information that it contains is useful.) IMC-2513 indicates that the fire protection program inspection (IP 64704) is part of the minimum inspection program on which the staff would base its decision on the applicant's readiness for operating license issuance. IP 64704 objectives are to (1) evaluate the overall adequacy and implementation of the licensee's approved fire protection program, (2) review the procedural incorporation and implementation of any changes permitted or required by the NRC in the fire protection program, and (3) determine the adequacy of the licensee's system for conducting programmatic changes necessitated by quality assurance audit results, generic deficiencies, or events. The inspection verifies that the licensee has developed technically adequate procedures to implement the entire fire protection program. In addition, it evaluates the implementation of the procedures, verifies the proper installation of fire protection systems, evaluates the readiness of licensee's personnel to prevent and fight fires, and evaluates the effectiveness of licensee controls.

The staff agrees with NEI that NRC review of detailed procedures is important to enable the staff to understand how program requirements are being met and to verify the adequacy of implementation. The procedures do not include all of the procedures that an applicant would have to develop, but, rather, are a subset of the overall procedures needed to operate the plant. This would also be true of implementing procedures for other programs that fall into Category C.

The staff understands that the implementing procedure review done in accordance with IP 64704 is needed in order to issue a COL without ITAAC for the fire protection program. If the fire protection procedures or similar information are not available during review of a COL application, then a reasonable assurance finding with respect to program adequacy at the COL stage is still possible based on the information normally contained in an FSAR; however, the staff believes that such a COL would need to include ITAAC to verify the development and implementation of the fire protection procedures.

III.b Use of Training Program as an Example

NEI's letter also provides an example related to the training program required by 10 CFR 50.120. NEI referenced words in an ongoing Part 52 rulemaking (see 68 FR 40025) that would clarify what information must be provided to support the issuing of the COL. In the proposed rule, the Commission proposed to revise the language in § 52.78 to clarify its requirements and to redesignate it as § 52.209. The proposed rule provides that the application must "describe" the training program required by § 50.120 in the application, and proposes a separate requirement for the combined license holder to establish and implement a training program. NEI states that it agrees with the distinction identified in the Part 52 proposed rule between "describing" programs in the COL application and "establishing and implementing" them prior to operation.

The staff disagrees with NEI. A fundamental assumption for the proposed rule was that ITAAC for training would be a condition of a COL. The staff does not intend to treat the training program any differently than the fire protection program. That is, if the training program procedures are not available during the review of the COL application, then a reasonable assurance finding at the COL stage is still possible based on the information discussed in the supplementary information of the proposed rule. However, the staff believes that such a COL would have ITAAC to verify the implementation of the training program. The staff notes that the proposed rule could be revised to require that the training program be implemented before a decision is made on a COL application, and no ITAAC would then be needed in accordance with the September 11, 2002, SRM.

III.c Litigation Risk Associated With the Post-Construction Hearing

The NRC staff asked if the industry's opposition to ITAAC on operational programs was motivated primarily by the desire to reduce litigation risk associated with the post-construction hearing. In its letter NEI stated the following to address the staff's question:

> The scope of the post-construction hearing corresponds to the scope of ITAAC, and so, as a general matter, the risk of litigation increases as the scope of ITAAC increases. This increase would be non-linear to the extent that additional ITAAC do not contain objective acceptance criteria. The industry fully accepts the litigation risk associated with the required scope of ITAAC; prospective applicants will weigh this risk and many other factors in making their business decision on a new nuclear plant project. We oppose ITAAC that are neither required nor necessary because such ITAAC add undue regulatory burden in the form of increased litigation risk in the post-construction hearing. As discussed above, ITAAC on programs are not required to support reasonable assurance findings at COL or to assure adequate protection of public health and safety prior to operation.

The staff believes that any issue relating to the adequacy of ITAAC for operational programs would properly be litigated only in the mandatory hearing on the COL application. If the mandatory hearing results in the issuance of a COL, the adequacy of the ITAAC in the COL, including those for operational programs, cannot subsequently be litigated in a hearing held pursuant to 10 CFR 52.103. Rather, in accordance with 10 CFR 52.103(f), a member of the

public who wishes to challenge the adequacy of ITAAC after a COL has been issued may file a petition pursuant to 10 CFR 2.206 requesting enforcement action with respect to the ITAAC. The industry may find acceptable the litigation risk associated with the mandatory hearing on whether the COL should be issued because this may occur at a stage before substantial resources have been dedicated to constructing a plant.

III.d Treatment of the Inservice Inspection and Inservice Testing Program

NEI commented during the workshop and in its letter about the staff's proposed Category E - an ITAAC for a program is not necessary because ITAAC will be dispositioned prior to fuel load and the program is not required to be implemented until after fuel load. The staff's proposal placed the maintenance rule and the inservice inspection and inservice test program in this category. NEI asked why, if the staff can make its reasonable assurance findings without ITAAC or procedure-level information on these programs, does the staff believe that ITAAC are needed on other programs?

The staff answered during the workshop that ITAAC are the sole basis for the decision that is made by the Commission on whether or not to authorize operation. Matters like the maintenance rule that take place after fuel load will be controlled by license conditions just like other operational issues that are performed after fuel loading like low-power testing. The staff also mentioned that when category E was developed, it considered how such programs would be handled under the 10 CFR Part 50 licensing process, which still can be used. Requirements such as the maintenance rule were promulgated after the last operating licenses were issued. The staff stated during the workshop that it envisioned license conditions associated with the implementation of these programs.

Staff Supplemental Response

The staff believes that under the 10 CFR Part 50 licensing process, the inservice inspection and inservice testing program and the maintenance rule would not be implemented until after issuance of an operating license and initial fuel load. Therefore, the adequacy of the implementation of these programs would not be ripe for a challenge in a hearing on an operating license application. For the same reason, implementation of these same programs prior to authorization to load fuel in accordance with 10 CFR Part 52 would also not be ripe for challenge. (It should be noted that the adequacy of the program description will be reviewed during the review of the application, which could result in license conditions governing implementation, all of which might be litigated at the mandatory COL hearing.) Therefore, the staff believes that by placing these programs in Category E, it is being consistent with how they would be treated under a Part 50 licensing process. The staff further believes that the rest of its categorization of programs is consistent with this philosophy.

IV. Changes to the Staff's Proposal Subsequent to the August 25, 2003, Workshop

Subsequent to the August 25, 2003, workshop, the staff determined that the term "quality assurance program" was too broad of a term. Consistent with the staff's original proposal, the staff determined that the quality assurance program description should be discussed in two phases. The two phases are: quality assurance during the design and construction phases and quality assurance during the operations phase. These two categories follow the guidance

contained in Sections 17.1 and 17.2 of NUREG-0800, “Standard Review Plan Review of Safety Analysis Reports for Nuclear Power Plants LWR Edition,” respectively.

For quality assurance during the design and construction phases, the staff believes that programmatic ITAAC are not necessary because hardware-related ITAAC address the results to which the program is directed. Therefore, this program is proposed to be placed in Category B of the staff’s proposal. Because there are no such hardware-related ITAAC for quality assurance during the operations phase the staff proposes that this program be placed in either Category C or D based on the availability of quality assurance operations phase program information prior to issuance of a COL

V. Conclusions

The staff has reviewed the comments that it received during the workshop and in the written responses to the FRN and has not made any changes to its proposal based on these responses. With the exception of clarifying the treatment of the quality assurance program, the staff did not change its proposal. The staff believes it needs Commission guidance on whether the staff’s approach to this matter fulfills the intent of the Commission’s SRM dated September 11, 2002. The staff believes that information beyond that normally contained in an FSAR is needed in order to issue a COL without ITAAC for programs that fall into Category C of its proposal, with such information being sufficient to verify implementation of those programs.